UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

In Re GLAXO SMITHKLINE PLC SECURITIES LITIGATION	:	05 Civ. 3751 (LAP)
	:	OPINION

LORETTA A. PRESKA, United States District Judge:

Lead Plaintiff Joseph J. Masters ("Plaintiff" or "Masters") brings this putative class action alleging that GlaxoSmithkline ("GSK") and GSK CEO and Chairman Jean-Pierre Garnier ("Garnier") (collectively "Defendants") violated section 10(b) of the Securities Exchange Act of 1934, 15 U.S.C. § 78j(b)(1994), and Rule 10b-5, 17 C.F.R. § 240.10b-5 (2001), by making various false and misleading statements resulting in damages to GSK investors during the class period. Defendants move to dismiss pursuant to Rule 12(b)(6) for failure to state a claim on which relief may be granted on grounds, inter alia, that certain claims are time-barred, and that Plaintiff has failed to plead fraud with particularity, failed to allege scienter, and failed to allege loss causation. For the reasons set forth below, Defendants' motion (dkt. no. 13) is granted, and the Consolidated Second Amended Complaint ("SAC") is dismissed with prejudice.

I. Background

This is a putative class action filed on behalf of individuals who acquired GSK common stock or American Depositary Receipts ("ADRs") during the period from December 27, 2000 to August 5, 2004 (the "Class Period"). (SAC ¶ 9). Plaintiff alleges that he acquired GSK securities during the Class Period and suffered damages as a result. (SAC ¶ 2). More specifically, according to his class representative certifications, Masters purchased 1,400 shares of GSK on September 28, 2001 at a share price of $56.28 and sold the same number of shares on June 13, 2002 at a price of $39.43. Plaintiff purchased an additional 350 shares of GSK on February 17, 2004 at a share price of $42.96 and had not sold those shares as of May 10, 2005.

GSK is a public company whose securities trade on the New York and London Stock Exchanges. (SAC ¶ 3). Garnier was CEO and Chairman of GSK throughout the Class Period. (SAC ¶ 4). The SAC alleges that on February 19, 2004, Garnier sold 142,250 shares of GSK stock for $6,143,293 based on material non-public information. (SAC ¶ 279).[1]

[1] The SAC also alleges that on December 14, 2004, Garnier sold 79,054 shares for $3,774,037, but this transaction occurred after the Class Period end date of August 4, 2004.

A. Procedural History

The initial complaint in this action was filed on April 12, 2005. Two additional actions, No. 05-cv-3885 and No. 05-cv-4723, were brought in this district on April 18, 2005 and May 16, 2005, respectively. A fourth related action, No. 05-cv-6231, was transferred here from the Eastern District of Pennsylvania.

By order dated July 25, 2005, this Court consolidated all four actions and granted Masters' unopposed motion for appointment as lead plaintiff. This Court also set up a procedure whereby Plaintiff was directed to serve a consolidated amended complaint, Defendants were to advise Plaintiff of perceived deficiencies, i.e., grounds for a motion to dismiss, and Plaintiff was given the opportunity to file a second amended complaint with the understanding that no further amendments would be permitted. The parties availed themselves of this procedure, and the SAC was docketed on April 6, 2006.

B. The Second Amended Complaint

The SAC alleges violations of the Exchange Act in two counts. The first count alleges that Defendants violated section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder by, inter alia, making untrue

statements of material fact that resulted in damages to Plaintiff and the class. (SAC ¶¶ 282-286). The second count alleges control person liability under section 20(a) of the Exchange Act as to Defendant Garnier. (SAC ¶¶ 287-291).

Broadly speaking, the SAC alleges that GSK violated the Exchange Act in four ways: 1) by misrepresenting the safety and efficacy of the use of its drug Paxil in children (the "Paxil Pediatric Allegations"); 2) by making false statements and omissions regarding the viability of GSK's patents for Paxil and Augmentin and engaging in a course of frivolous litigation with respect to those patents (the "Patent Allegations"); 3) by suppressing information about Paxil's addictiveness and withdrawal effects (the "Paxil Withdrawal Allegations"); and 4) by violating the Federal False Claims Act by overcharging Medicare and Medicaid for GSK's pharmaceutical products, resulting in multiple lawsuits against GSK (the "False Claims Act Allegations"). The SAC also alleges that Garnier sold GSK stock based on material, non-public information (the "Insider Trading Allegations"). (SAC ¶ 279).

1. The Paxil Pediatric Allegations

GSK manufactured and sold paroxetine under the name Paxil in the United States and Seroxat in Great Britain (hereinafter "Paxil") throughout the Class period. (SAC ¶ 18). Paxil is a selective serotonin re-uptake inhibitor ("SSRI") that is approved by the FDA for treatment of depression, anxiety and other conditions in adults. (Id.). Paxil has not been approved by the FDA for treatment of any conditions in children or adolescents. (Id.). Physicians, however, are permitted to prescribe FDA-approved drugs for non-FDA-approved uses where, through the exercise of independent judgment, they determine that the prescription is appropriate. (Id.). This practice is referred to as an "off-label" use. (Id.). GSK reported Paxil sales of £1.55 billion for the year 2000. (SAC ¶ 31). In 2002, Paxil prescriptions to treat children and adolescents totaled $55 million in the United States and "much more" worldwide. (SAC ¶ 19).

The SAC alleges that GSK misrepresented the safety and efficacy of Paxil in treating Major Depressive Disorder ("MDD") in children by allowing positive information about Paxil to be disclosed publicly but withholding or concealing negative information. (SAC ¶ 20). More specifically, the SAC alleges that on various occasions

prior to and during the Class Period, research scientists sponsored by or known to GSK published articles and presented posters at research conferences reporting on the safety and efficacy of Paxil for treatment of children and adolescents. (SAC ¶¶ 22-29, 32-47).

The SAC also alleges that GSK made misrepresentations about Paxil by allowing dissemination of a study that showed mixed results about the safety and efficacy of Paxil but withholding the results of studies that had negative results. (SAC ¶¶ 58-80). Two out of three placebo-controlled studies conducted by GSK, studies 377 and 701, showed no statistically significant difference between the effectiveness of Paxil and the effectiveness of the placebo. (SAC ¶ 67). A third study, study 329, presented a mixed picture, with Paxil failing to outperform the placebo on two primary measures of efficacy but outperforming the placebo on three out of five secondary measures of efficacy. (SAC ¶ 68). In all three studies, suicidal thoughts and acts, as well as mood swings and crying (behavior coded as "emotional lability") were significantly higher in the Paxil group compared to the placebo group. (SAC ¶ 70). Specifically, study 329 showed emotional lability in 6.5% of the Paxil group compared with 1.1% of the control group. (Id.); study 377 showed emotional

lability in 4.4.% of the Paxil group compared with 3.2% of the control group; and study 701 showed emotional lability in 3.6% of the Paxil group compared with 1.4% of the control group. (Id.)

The SAC alleges that GSK disseminated the results of study 329, concealing or downplaying its negative aspects, but suppressed dissemination of the other studies. (SAC ¶¶ 58-62, 73-80). After GSK submitted studies 329, 377 and 701 to the FDA in connection with an application for approval of Paxil to treat Obsessive Compulsive Disorder ("OCD") in children and adolescents, various regulatory agencies in the United States and abroad issued warnings against the use of Paxil in children and adolescents. (SAC ¶¶ 81-90).

With regard to loss causation, the SAC specifies two price drops of GSK securities following the release of information to the public about Paxil's adverse effects on children. On June 2, 2004, the New York State Attorney General announced a lawsuit against GSK based on suppression of the adverse pediatric studies, resulting in a price drop from $42.77 to $41.39, or $1.38 per share, on that date. (SAC ¶ 48). On December 9, 2004, the ABC News program Primetime Live aired a story about the adverse effects of Paxil on children, resulting in a stock price

drop from $45.08 to $44.82, or 23 cents per share, the following day. (SAC ¶ 51).

2. The Paxil Withdrawal Allegations

The SAC alleges that GSK engaged in a "disinformation campaign" designed to suppress information about the withdrawal effects of Paxil. (SAC ¶ 238). The SAC alleges that GSK knew from pre-marketing studies that Paxil had higher addictive potential than other SSRIs. (SAC ¶¶ 240-242). Despite this alleged awareness, GSK included in its promotional literature the following statement: "Paxil belongs to a class of medications called SSRIs, which have not been shown to be associated with addiction." (SAC ¶ 243). The SAC catalogues 18 scientific studies or reports between 1993 and 2000 documenting withdrawal symptoms as a result of Paxil discontinuation, none of which was acted upon. (SAC ¶¶ 246-263).

In August 2001, a class action was filed in California on behalf of consumers addicted to Paxil. (SAC ¶ 238). The SAC alleges that on September 6, 2001, GSK's share price fell from $45.14 to $44.10, or $1.04 per share, on news of the class action suit alleging that Paxil caused withdrawal symptoms. (SAC ¶ 264). In December 2001, the FDA ordered GSK to begin warning patients about Paxil's withdrawal

symptoms, and the company rewrote Paxil's warning label to include "discontinuation effects." (SAC ¶ 265).

3. The Patent Allegations

Broadly speaking, the Patent Allegations allege that GSK misled investors by issuing statements misrepresenting the validity and duration of GSK's patents for Paxil and Augmentin. The Patent Allegations allege that GSK engaged in a course of baseless patent filings and frivolous patent litigation.

With regard to Augmentin, the SAC alleges that in a July 26, 2000 Financial Times article, Garnier stated that a newly granted patent on Augmentin would extend patent protection to 2013. (SAC ¶ 132). After a federal court ruled on February 2, 2002 that GSK lost certain patent protections for Augmentin, Garnier appeared for a CNBC interview and said, "We are very confident we can defend our patents." (SAC ¶ 134). Garnier also stated, "The PTO confirmed that those patent[s] were genuine, they were rock solid. And we feel that the courts eventually will recognize the letter of the law and give us the added protection for Augmentin." (Id.). On February 25, 2002, a federal district court ruled that GSK's '380 patent for Augmentin was invalid. (SAC ¶ 137). On November 23, 2003,

the Federal Circuit upheld the district court's ruling that GSK did not have patent protection for Augmentin. (SAC ¶ 141).

Regarding loss causation, the SAC alleges that after a March 13, 2002 announcement that GSK had lost part of its court battle over Augmentin, GSK's share price fell from $48.81 on March 13, 2002 to $48.27 on March 14, 2002, and to $47.62 on March 15, 2002, a total of $1.19 per share in two days. (SAC ¶ 138). When GSK announced on May 23, 2003 that it lost patent protection for Augmentin completely, GSK's share price fell from $41.47 to $38.03, or $3.44 per share. (SAC ¶¶ 139-140, 174-175).

The SAC alleges that GSK represented in its Form 20-F for the years 1999 through 2001 that its patent protection for Paxil expired in 2006. (SAC ¶¶ 99, 103). The SAC alleges that this representation was false because the patent protection was based upon "evergreening," i.e., obtaining frivolous patents in order to extend patent life. (SAC ¶ 111). More specifically, the SAC alleges that GSK attempted to protect Paxil from generic competition by filing additional patents "concerning chemical properties of the molecule that have nothing to do with its effectiveness." (Id.).

The SAC alleges that GSK filed numerous baseless patent infringement lawsuits against competitors who sought to market generic forms of Paxil. (SAC ¶¶ 104-108, 158-161, 202-227). With regard to loss causation, the SAC describes six stock price drops following negative news about Paxil's patent protection.

After the Financial Times reported on Saturday July 13, 2002 that the German company BASF prevailed in court and won the right to produce generic versions of Paxil, GSK shares fell from $38.15 to $36.65 on Monday July 15, 2002. (SAC ¶ 165). When GSK announced on July 23, 2002 that it lost a Paxil patent case in the United States, GSK's stock fell from $34.02 to $32.86, or $1.16 per share. (SAC ¶ 166). On October 24, 2002, GSK's share price dropped from $41.34 to $39.27, or $2.07 per share, on news that GSK had reserved £145 million for legal costs. (SAC ¶ 169). Following a court ruling on March 4, 2003 that competitor Apotex did not infringe GSK's patent on Paxil, GSK's stock price fell from $35.27 to $34.15, or $1.12 per share. (SAC ¶ 173). When Apotex received FDA approval on July 31, 2003 to market a generic version of Paxil, GSK's stock price fell from $39.22 to $37.40, or $1.82 per share. Finally, when GSK announced on February 12, 2004 that Paxil sales were down by 40% because

of generic competition, GSK's share price fell from $45.15 to $42.52, or $2.63 per share. (SAC ¶ 179).

4. The False Claims Act Allegations

The SAC's False Claims Act Allegations are brief, comprising only three paragraphs, and are focused on lawsuits against GSK for False Claims Act violations. The SAC alleges that GSK was sued for False Claims Act violations several times, starting with an action brought on November 16, 2001, when GSK was trading at $53.96 per share. (SAC ¶ 276). After news of the suit was reported in the National Law Journal on December 10, 2001, GSK's share price is alleged to have fallen to $49.40 on December 11, 2001, but the complaint is silent about what the share price was on December 10, 2001. (Id.) The SAC states that the lawsuits claimed that GSK was charging the government (i.e., Medicare and Medicaid) higher prices for drugs than it charged private entities. (SAC ¶¶ 276-277). GSK announced settlement of its False Claims Act liabilities for $87,600,922 on April 16, 2003, resulting in a stock price drop from $39.10 on April 14, 2003 to $37.60 on April 16, 2003, or $1.50 per share.

5. The Insider Trading Allegations

With respect to all of the above claims, the SAC alleges that Garnier took advantage of material adverse information not known to the public while issuing materially false and misleading statements. (SAC ¶ 279). The SAC alleges that the extent and timing of Garnier's trades establish that he possessed materially adverse information that he failed to disclose. (Id.). The only Garnier stock transaction during the Class Period alleged in the SAC is a sale of 142,250 shares of GSK on February 19, 2004, yielding proceeds of $6,143,293.

II. Applicable Law

A. Standard of Review

On these motions to dismiss the complaint, the Court accepts the factual allegations in the complaint and draws all inferences in favor of Plaintiff. Karedes v. Ackerly Group, 423 F.3d 107, 113 (2d Cir. 2005). It is well-settled that a case may not be dismissed "unless the court is satisfied that the complaint cannot state any set of facts that would entitle the plaintiff to relief." Miller v. Wolpoff & Abramson, 321 F.3d 292, 300 (2d Cir. 2002)(citing Patel v. Contemporary Classics of Beverly

Hills, 259 F.3d 123, 126 (2d Cir. 2001). The Court, however, need not give "credence to plaintiff's conclusory allegations" or legal conclusions offered as pleadings. Cantor Fitzgerald v. Lutnik, 313 F.3d 704, 709 (2d Cir. 2002) (citing Dawes v. Walker, 239 F.3d 489, 491 (2d Cir. 2001)); Van Carpals v. S.S. American Harvester, 297 F.2d 9, 11 n.1 (1961) (Friendly, J.) ("[I]n federal pleading there is no need to plead legal conclusions; these are for the court to apply."). On a motion to dismiss pursuant to Fed. R. Civ. P. 12(b)(6), the Court may consider materials of which the plaintiff had notice and relied upon in framing his complaint, as well as materials of which judicial notice may be taken. See Kavowras v. New York Times, 328 F.3d 50, 57 (2nd Cir. 2003); Cortec Indus. v. Sum Holding, 949 F.2d 42, 48 (2d Cir. 1991).

B. Section 10(b) Elements and Pleading Requirements

Section 10(b) of the Exchange Act makes it unlawful to "use or employ, in connection with the purchase or sale of any security . . . any manipulative or deceptive device or contrivance" in violation of Securities and Exchange Commission ("SEC") rules and regulations. 15 U.S.C. § 78j(b). The SEC implementing rule, Rule 10b-5, 17 C.F.R. § 240.10b-5 (2004), prohibits the making of untrue material

statements of fact or the misleading omission of material facts in connection with the purchase or sale of securities. Courts have implied a private right of action from section 10(b) and Rule 10b-5, with the following basic elements: 1) a material misrepresentation or omission; 2) scienter or "wrongful state of mind;" 3) a connection with the purchase or sale of a security; 4) reliance; 5) economic loss; and 6) loss causation. See Dura Pharmaceuticals v. Broudo, 544 U.S. 336, 341-42 (2005). In other words, to state a claim for securities fraud, "a plaintiff must plead that 'in connection with the purchase or sale of securities, the defendant, acting with scienter, made a false material misrepresentation or omitted to disclose material information and that plaintiff's reliance on defendant's action caused [plaintiff's] injury.'" In Re Time Warner Inc. Securities Litigation, 9 F.3d 259, 264 (2d Cir. 1993) (quoting Bloor v. Carro, Spanbock, Londin, Rodman & Fass, 754 F.2d 57, 61 (2d Cir. 1985).

"A complaint asserting securities fraud must also satisfy the heightened pleading requirement of Federal Rule of Civil Procedure 9(b), which requires fraud to be alleged with particularity." Kalnit v. Eichler, 264 F.3d 131, 138 (2d Cir. 2001) (citing Ganino v. Citizens Utilities Co., 228 F.3d 154, 168 (2d Cir. 2000). The Private Securities

Litigation Reform Act of 1995 ("PSLRA"), Pub. L. No. 104-67, 109 Stat. 737, heightened the requirements for pleading securities fraud. Id. It also protected forward-looking statements in a company's SEC filings and press releases from giving rise to a securities fraud claim as long as the statements are identified as forward-looking and are accompanied by sufficient cautionary language. See 15 U.S.C. § 78u-5(c)(1)(A)(i). Similarly, under the "bespeaks caution" doctrine, "[c]ertain alleged misrepresentations . . . are immaterial as a matter of law because it cannot be said that any reasonable investor could consider them important in light of adequate cautionary language." In re Bausch & Lomb, Inc. Sec. Litig., No. 01-CV-6190-CJS, 2003 WL 23101782, at *2 (W.D.N.Y. Mar. 28, 2003) (quoting Halperin, 295 F.3d at 357); see also Mercury Air Group, Inc. v. Jet USA Airlines, Inc., No. 97 Civ. 3473, 1998 WL 542291, at *4-*5 (S.D.N.Y. Aug. 26, 1998), aff'd, 189 F.3d 461 (2d Cir. 1999).

The PSLRA also specifies the standard for pleading scienter:

> In any private action arising under this chapter in which the plaintiff may recover money damages only on proof that the defendant acted with a particular state of mind, the complaint shall, with respect to each act or omission alleged to violate this

> chapter, state with particularity facts giving rise to a strong inference that the defendant acted with the required state of mind.

15 U.S.C. § 78u-4(b)(2); Kalnit, 264 F.3d at 138. To meet the PSLRA requirement for alleging scienter, a securities fraud complaint must set forth allegations "giv[ing] rise to a strong inference of fraudulent intent." Id. (quoting Novak v. Kasaks, 216 F.3d 300, 307 (2d Cir. 2000)). "A plaintiff can establish this intent either (a) by alleging facts to show that defendants had both motive and opportunity to commit fraud, or (b) by alleging facts that constitute strong circumstantial evidence of conscious misbehavior or recklessness." Id. at 138-39 (citations and internal quotation marks omitted).

Where a plaintiff alleges securities fraud against a public company and its officers and directors, it is motive rather than opportunity that is at issue. See, e.g., Kalnit, 264 F.3d at 139; In Re Time Warner, 9 F.3d at 269. Kalnit explained that in order to allege motive to commit fraud, a section 10(b) complaint must set forth something more than a generalized "assertion that the officers were motivated to inflate the value of stock to increase their executive compensation." Kalnit, 264 F.3d at 139. In other words, a plaintiff who alleges that directors or officers

misled the public in order to profit from an inflated stock price must point to a "specific benefit that would inure to the defendants that would not be either generalized to all corporate directors or beneficial to all shareholders[.]" Id. at 142. Concrete, personal benefits giving rise to a strong inference of fraudulent intent must be alleged. Id. at 139. Allegations of stock sales by insiders are insufficient to establish scienter in the absence of factual allegations demonstrating that such sales were unusual in timing or amount. See, e.g., Rothman v. Gregor, 220 F.3d 81, 94-95 (2d Cir. 2000); In re Glenayre Techs., Inc. Sec. Litig., No. 96 Civ. 8252, 1998 WL 915907, at *4 (S.D.N.Y. Dec. 30, 1998) ("Insider stock sales are [only] unusual where the 'trading was in amounts dramatically out of line with prior trading practices [and] at times calculated to maximize personal benefit from undisclosed inside information.'") (citation omitted), aff'd sub nom. Kwalbrun v. Glanayre Techs., Inc., 201 F.3d 431 (2d Cir. 1999); In re Health Mgmt. Sys. Inc. Sec. Litig., No. 97 Civ. 1865, 1998 WL 283286, at *6 n.3 (S.D.N.Y. June 1, 1998); see also Ressler v. Liz Claiborne, Inc., 75 F.Supp. 2d 43, 60 (E.D.N.Y. 1999).

"'Where motive is not apparent, it is still possible to plead scienter by identifying circumstances indicating

conscious behavior by the defendant, though the strength of the circumstantial allegations must be correspondingly greater.'" Id. at 142 (quoting Beck v. Mfrs. Hanover Trust Co., 820 F.2d 46, 50 (2d Cir. 1987). A plaintiff who pleads conscious misbehavior or recklessness must allege that defendant engaged in "'conduct which is highly unreasonable and which represents an extreme departure from the standards of ordinary care[.]'" Id. (quoting Honeyman v. Hoyt (In Re Carter Wallace, Inc., Secs. Litig.), 220 F.3d 36, 39 (2d Cir. 2000).

In Dura, supra, the Supreme Court clarified the requirements for pleading economic loss and loss causation under the Exchange Act. Noting that the implied cause of action available under section 10(b) resembles a common law tort cause of action for deceit (i.e., fraudulent misrepresentation), Dura, 544 U.S. at 343-344, the Court held that a plaintiff who brings an action under section 10(b) must "allege and prove the traditional elements of causation and loss," id. at 346. Put simply, a plaintiff must allege that he suffered a loss, id. at 344, and that "the defendant's misrepresentation proximately caused the plaintiff's economic loss," id. at 346.

In Dura, the complaint lacked this element because it alleged merely that the defendant had made

misrepresentations and that the plaintiff had purchased stock at an artificially high price. See id. at 339-40. "The complaint[] fail[ed] to claim that Dura's share price fell significantly after the truth became known[.]" Id. at 347. The loss causation inquiry, therefore, must focus on a link between dissemination of information about the alleged misrepresentations and significant drops in share price. Needless to say, the inquiry must also include whether the complaint alleges that Plaintiff suffered a loss.

C. Statute of Limitations

Section 804(1) of the Public Company Accounting Reform and Investor Protection Act of 2002 ("Sarbanes-Oxley"), codified in part at 28 U.S.C. § 1658(b), extended the statute of limitations period applicable to section 10(b) and Rule 10b-5 to the earlier of "(1) two years after the discovery of the facts constituting the violation; or (2) 5 years after such violation." The two-year limitations period, or the "inquiry notice" period, applies when "'circumstances would suggest to an investor of ordinary intelligence the probability that she has been defrauded[.]'" LC Capital Partners v. Frontier Ins. Group,

318 F.3d 148, 154 (2d Cir. 2003) (quoting Dodds v. Cigna Securities, Inc., 12 F.3d 346, 350 (2d Cir. 1993).

The circumstances giving rise to inquiry notice in the securities litigation context are frequently compared to "storm warnings." Lentell v. Merrill Lynch & Co., 396 F.3d 161, 168 (2d Cir. 2005). "Where . . . the facts needed for determination of when a reasonable investor of ordinary intelligence would have been aware of the existence of a fraud can be gleaned from the complaint . . . , resolution of the issue on a motion to dismiss is appropriate." LC Capital, 318 F.3d at 156.

III. Discussion

A. Statute of Limitations

The parties agree that, under Sarbanes-Oxley, the statute of limitations for an Exchange Act claim is the shorter of five years from the occurrence or two years from the time plaintiff had actual or inquiry notice of the claim. See 28 U.S.C. § 1658(b). They also agree that the two-year period begins to run as soon as "'circumstances would suggest to an investor of ordinary intelligence the probability that she had been defrauded.'" LC Capital, 335 F.3d at 193 (quoting Dodds, 12 F.3d at 350).

The first action in this litigation was filed on April 12, 2005. Assuming for these purposes that the Paxil Discontinuation Allegations, the Patent Allegations, and the False Claims Act Allegations state a claim under section 10(b), plaintiff was on notice of the facts underlying those claims more than two years earlier, thus any claim arising from those allegations is barred by the statute of limitations.

The Paxil Discontinuation Allegations assert that, from the early 1990s until August 2001, GSK withheld from physicians and the market information about alleged difficulties experienced by patients taking Paxil who attempted to discontinue use of the drug. (SAC ¶¶ 238, 264). The SAC further alleges that in December 2001, GSK, in consultation with the FDA, changed the labeling of Paxil to include a warning about such effects and the FDA approved the new label. (SAC ¶ 265). Moreover, the SAC alleges that disclosure of the discontinuation effects caused the price of GSK ADRs to drop by $1.04 on September 6, 2001, following the news of the consumer class action lawsuits. (SAC ¶ 264). Thus, even according to the SAC, plaintiff was on notice of any claim based on the Paxil Discontinuation Allegations well more than two years before this lawsuit was commenced. To the extent that

plaintiff argues that the consumer actions did not constitute storm warnings because they were not brought by shareholders, (Pl. Mem. at 23), it is a distinction without a difference. The alleged fraudulent conduct -- failing to disclose the withdrawal effects of Paxil -- is the same.

The allegations of the SAC also show that any claim based on the Patent Allegations is time-barred. The Patent Allegations allege that GSK brought patent litigations seeking to prevent generic drug manufacturers from manufacturing and selling generic versions of Paxil and Augmentin beginning in 1998. (SAC ¶¶ 104, 161). The SAC alleges that in February 2002, at least one court had invalidated certain of GSK's patents covering Augmentin and that information was publicly disclosed no later than March 13, 2002. (SAC ¶¶ 133-134, 137-138). Similarly, on July 23, 2002, GSK announced that it had lost one patent case involving Paxil and on December 30, 2002, GSK publicly disclosed that a different court granted summary judgment in favor of GSK on one patent claim, granted summary judgment against GSK on a different patent, and declined to grant summary judgment to either party on two additional patents. (SAC ¶¶ 110, 166). All of those developments were disclosed, at the latest, in GSK's Form 20-F for the year

ending December 31, 2002, which was filed with the SEC on March 28, 2003. (2002 Form 20-F at 103-107).

In July 2002, the FTC issued a report critical of GSK's conduct in pursuing patent listings. (SAC ¶ 231). The SAC also alleges that GSK was sued in private antitrust actions arising out of its patent enforcement activities -- litigations that were disclosed, at the latest, in GSK's Form 20-F for the year ending December 31, 2002. (SAC ¶ 99; 2002 Form 20-F at 106). The SAC alleges that GSK stock price dropped on at least five different occasions between April 1, 2002 and March 4, 2003 in response to developments in the patent litigation. Indeed, the SAC quotes a March 5, 2003 article published in The Times (London) that "the bad news [concerning the loss of patent protection for Paxil] is fully in the price." Here again, there can be no dispute that plaintiff was on notice of any claim arising from the Patent Allegations more than two years before this action was filed. See, e.g., Menowitz v. Brown, 991 F.2d 36, 42 (2d Cir. 1993). In any event, because, as noted below, the underlying facts about the patent litigations were all publicly available, there is no doubt that plaintiff was on inquiry notice long before April of 2003, and inquiry would have disclosed all of the facts he relies on now.

To the extent that plaintiff argues, based on LC Capital, that Garnier's "reassuring words" that GSK would prevail on its patent litigation somehow toll the statute of limitations, that case is of no assistance. There, the corporate officer announced that the recurring problem of under-reserving "is now behind us" and that the company had "paid the bill" on those items. LC Capital, 318 F.3d at 155. The court noted that the problem of under-reserving was a serious one for the company, an insurance company, and that it had recurred. But, because the "'reassuring' statements by management were mere expressions of hope, devoid of any specific steps taken to avoid under-reserving in the future," the court found that "the claimed reassurances are unavailing." Id. at 156.

The logic of LC Capital applies with even greater force here. Garnier's statements ("We are very confident we can defend our patents[,]" and "The PTO confirmed that those patent[s] were genuine, they were rock solid. And we feel that the courts eventually will recognize the letter of the law and give us the added protection for Augmentin." (SAC ¶ 134)), can be viewed by a reasonable investor only as mere expressions of hope. The company had no ability to assure the result of the patent litigations, whereas at least in LC Capital the company had some ability to avoid

under-reserving. Also the words used, "we are very confident" and "we feel," can only be understood as aspirational, and thus no reasonable investor would understand them to be factual guarantees of patent protection. Accordingly, these supposed "reassuring" words are insufficient to toll the statute of limitations.

Finally, the SAC alleges that GSK "has also violated the Federal False Claims Act numerous times," that it was sued as a result of those violations on November 16, 2001, and that public disclosure of a False Claims Act lawsuit caused a drop in share price on December 11, 2001. (SAC ¶276). Because plaintiff had notice of GSK's alleged violations of the False Claims Act more than two years before bringing this action, any claim arising from those allegations is time-barred.[2] Accordingly, based on the allegations of the SAC and publicly-filed documents, claims based on the Paxil Discontinuance Allegations, the Patent Allegations and the False Claims Act Allegations are time-barred.

[2] The SAC also alleges that GSK agreed to pay $150 million to settle False Claims Act claims involving two additional drugs on September 20, 2005. That allegation cannot give rise to a claim because it occurred more than a year after the end of the alleged Class Period.

B. Material Misrepresentation or Omission

The crux of the Paxil Pediatric Allegations is that GSK, through employees and sponsored researchers, disseminated information to the medical community about the most promising of its studies on Paxil's effects on children, while suppressing information about several negative studies. Assuming without deciding that 1) Plaintiff's allegations that GSK "sponsored" the doctors' research, (see SAC ¶¶ 34, 47), are sufficient to attribute the doctors' statements to GSK, see, e.g., Wright v. Ernst & Young LLP, 152 F.3d 169, 174-75 (2d Cir. 1998); SEC v. Pimco Advisors Fund Mgmt. LLC, 341 F.Supp.2d 454, 466 (S.D.N.Y. 2004) ("[A] defendant must actually make a false or misleading statement in order to be held liable under Sections 10(b)."") (quoting Wright, 152 F.3d at 175), and 2) articles in medical journals and presentations at medical conferences are statements made in connection with the purchase or sale of securities, see In re Carter Wallace, Inc. Sec. Litig., 150 F.3d 153, 156 (2d Cir. 1998) (holding that allegedly misleading advertisements in medical journals could satisfy the "in connection with" requirement where plaintiffs alleged those advertisements were intended to impact stock price, but affirming dismissal of securities fraud claim because alleged

misrepresentations were not material), the Paxil Allegations still fail because they are not material.

In order to be material, a pharmaceutical company's failure to disclose information about a drug must be of sufficient magnitude that the commercial viability of the drug would be called into question if the truth were disclosed. In Re Carter Wallace, 150 F.3d at 158. The SAC concedes that Paxil was a drug approved for adults, that prescriptions for children were an "off-label" use representing a small fraction of total sales, and that generic competitors were fighting to get a piece of Paxil's market share even after news about Paxil's effects on children came to light. The potential loss of a nominal amount of off-label sales certainly did not threaten the commercial viability of the drug, and thus the failure to disclose that potential loss cannot be said to be material. Because on the face of the SAC the alleged misrepresentations and omissions regarding Paxil's use in children are not material, the Paxil Pediatric Allegations fail to state a claim.

The Paxil Withdrawal Allegations similarly fail to allege a material misrepresentation or omission. The only decline in share price alleged to flow from revelations about Paxil withdrawal symptoms was a drop from $45.14 to

$44.10 on September 6, 2001 following the announcement of a class action lawsuit. As with the Paxil Pediatric Allegations, the SAC fails to allege that withdrawal symptoms threatened the commercial viability of Paxil, and therefore the alleged misrepresentations and omissions cannot be found to be material. Thus, the Paxil Withdrawal Allegations fail to state a claim.

Although the loss of patent protection would appear to meet the materiality element, the Patent Allegations fail to allege a misrepresentation or omission. As noted above, the Patent Allegations concern statements made by GSK about the legal positions the company was taking with respect to patent protection for Paxil and Augmentin and Garnier's "confiden[ce]" in the outcome. As to the former, there is simply nothing in the SAC that alleges that GSK misrepresented the legal positions it was taking or that GSK misrepresented developments in its patent cases as they occurred. To hold that a legal position taken by a publicly traded company, or an expression of confidence in a legal position, may be converted by hindsight into an actionable misrepresentation if the company later loses the lawsuit would have a chilling effect on publicly traded companies seeking to defend their interests in litigation. In any event, Garnier's and GSK's optimism that GSK would

prevail in the litigation is a classic example of a forward-looking statement and is clearly protected as such. See In re Bausch & Lomb, Inc. Sec. Litig., No. 01-CV-6190-CJS, 2003 WL 23101782, at *2 (W.D.N.Y. Mar. 28, 2003) (quoting Halperin v. eBanker USA.com, Inc., 295 F.3d 352, 357 (2d Cir. 2002)); see also Mercury Air Group, Inc. v. Jet USA Airlines, Inc., No. 97 Civ. 3473, 1998 WL 542291, at *4-*5 (S.D.N.Y. Aug. 26, 1998), aff'd, 189 F.3d 461 (2d Cir. 1999)).

In any event, GSK's regulatory filings fully disclosed to investors like plaintiff all of the Company's material information about the patent litigations. For example, GSK's Form 20-F for the year ended December 31, 2002 fully disclosed, among other litigation, the patent litigation involving Paxil and Augmentin. For example, the "Joint Statement by the Chairman and Chief Executive Officer" of GSK at the very beginning of the Form 20-F explained that:

> In July [2002], in the USA, the first generic version of *Augmentin* was launched. This followed a ruling by a federal judge that our *Augmentin* patents were invalid. We are appealing against the decision, in the firm belief that our patents are valid.
>
> . . .
>
> *Seroxat/Paxil* continues to be subject to threat of generic competition, particularly in the USA.

> A federal judge in Chicago recently ruled that GlaxosmithKline's patent in the USA covering the hemihydrate form of *Paxil* was valid but not infringed by generics company Apotex's product. We believe our patent to be infringed by Apotex's product and will appeal against the ruling. Also, we will continue to pursue litigation for infringement of other patents relating to *Paxil* against Apotex and other generics companies in the USA.
>
> As a result of these pending matters, the possible timing of generic competition to *Paxil* in the USA is unclear.

(2002 Form 20-F at 4). The "Legal Proceedings" section of the Form 20-F provided additional details of the patent litigations:

> In the USA a number of distributors of generic drugs have filed applications with the FDA to market generic versions of *Paxil/Seroxat* (paroxetine hydrochloride) prior to the expiration in 2006 of the Group's patent on paroxetine hydrochloride hemihydrate. The distributors are looking to bring to market anhydrate or other versions of paroxetine hydrochloride and in one case paroxetine mesylate. The cases are complex but the Group believes that the generic anhydrate and other versions infringe because they contain and/or convert to the hemihydrate form and/or infringe other Group patents. In response the Group has filed actions against all those distributors for infringement of various of the Group's patents.

(2002 Form 20-F at 103). The Form 20-F continued by identifying each of those patent litigations and describing the significant developments in each case--including that GSK had lost one case after trial because the judge had concluded that the generic company's product did not infringe the GSK patent, and that GSK was appealing that ruling. (2002 Form 20-F at 103). In the face of these disclosures in GSK's SEC filings, no reasonable investor can claim to have been deceived into believing that Paxil and Augmentin would remain free of generic competition until 2006 or beyond. See In re Bausch & Lomb, 2003 WL 23101782, at *2; Halperin, 295 F.3d at 357.

The False Claims Act Allegations fail to state a claim upon which relief may be granted because the SAC fails to allege a misrepresentation made by Defendants. The SAC alleges that GSK overcharged Medicare and Medicaid for certain drugs, resulting in lawsuits against GSK under the False Claims Act. (SAC ¶¶ 276-278).

The only alleged misleading statement cited is GSK's April 16, 2003 announcement that it had settled its False Claims Act liabilities by paying $87,600,922 for overcharges on Paxil and Flonase. Plaintiff alleges that this statement was misleading because the settlement did not represent all of GSK's liabilities under the False

Claims Act, referring to a September 20, 2005 report that GSK would pay $150 million to settle False Claims Act liabilities for overcharging the Government for two other drugs, Zofran and Kytril. The SAC, however, alleges no connection between these two settlements, two and a half years apart, involving different drugs. In any event, in light of GSK's annual revenue of £1.55 billion in 2000 on Paxil sales alone, (SAC ¶ 31), these settlement amounts are unlikely to be material.

C. Scienter

The SAC fails to plead scienter with the requisite particularity prescribed by the PSLRA. The SAC recites dozens of statements, identifies the speakers and states the approximate dates and locations where those statements were made but fails to explain why the alleged misstatements were fraudulent, how any of the statements affected the price of GSK stock or how any plaintiff was damaged by any statement.

With respect to the Paxil Pediatric Allegations, for example, the SAC lists numerous presentations made at medical conferences by independent doctors and researchers over an approximately five-year period concerning the doctors' views as to the potential benefits of using Paxil

to treat children and adolescents and alleges that GSK "sponsored" or "knew of" those presentations. Critically, however, the SAC does not allege that the doctors presented information knowing it was false, that the doctors did not in fact believe in the benefits of Paxil or how any of the doctors would have the motive to misrepresent the benefits of Paxil to the medical community. Accordingly, the Paxil Pediatric Allegations are insufficient.

The same result obtains as to the claim based on Garnier's trading. Although Garnier, like all CEOs, had the opportunity to commit fraud, the SAC fails to allege motive adequately. Plaintiff relies on the allegation that Garnier took advantage of information withheld from the public in order to sell shares of GSK at an artificially high price. As noted above, however, allegations of stock sales by insiders are insufficient absent allegations demonstrating that such sales were unusual in timing or amount. See, e.g., Rothman, 220 F.3d at 94-95.

During the Class Period, Garnier is alleged to a have executed a single sale of 142,250 shares on February 19, 2004. Of the thirteen share price declines alleged in the SAC, eleven occurred between September 6, 2001 and February 13, 2004, i.e., prior to the February 19, 2004 stock sale. (See SAC ¶¶ 138-140, 165-166, 169, 173, 177,

179, 264, 276-277). Two drops in share price are alleged to have occurred after February 19, 2004, on June 2, 2004 and December 10, 2004, respectively, (see SAC ¶¶ 48, 51), but the net effect of these two alleged declines in share price turns out, upon closer examination, to be an increase in share price. According to the SAC, as negative news hit the market about the Paxil's effects on children, GSK stock fell from $42.77 to $41.39 on June 2, 2004, then again from $45.08 to $44.82 on December 10, 2004. If anything is to be drawn from the facts alleged in the SAC, it is that Garnier held GSK stock through eleven price declines that resulted from negative news reaching the market, then sold a large number of GSK shares prior to a period of time in which the stock rose from $42.77 to $44.82 in the face of some additional negative information. Under these circumstances, the SAC fails to allege motive.

In any event, the public record discloses that Garnier's February 2004 sale was in connection with his exercise of stock options granted in 1994 that would expire unless exercised by November 22, 2004. Garnier sold only the number of ADRs necessary to pay the option price and applicable taxes and retained the remaining ADRs. Consequently, Garnier's net holdings of GSK increased by 88,802 ADRs as a result of the transaction, he continued to

own 204,430 ADRs (worth in excess of $8 million) as of December 31, 2004 and had options to purchase an additional 3.8 million ADRs. See Form 6-K dated February 20, 2004; Form 20-F for the year ended December 31, 2004 at 53-54. In these circumstances, Garnier's stock sale cannot be said to have been unusual or suspicious.

In order to allege scienter under the alternative theory of conscious misbehavior or recklessness, the complaint must present strong circumstantial evidence. Kalnit, 264 F.3d at 142. "'Where motive is not apparent, . . . the strength of the circumstantial allegations [of conscious misbehavior or recklessness] must be correspondingly greater.'" Id. (quoting Beck v. Mfrs. Hanover Trust Co., 820 F.2d 46, 50 (2d Cir. 1987). As noted above, see supra Part IV.A, Plaintiff has failed even to allege a material misrepresentation with respect to any of his allegations. Plaintiff falls far short of alleging "'conduct which is highly unreasonable and which represents an extreme departure from the standards of ordinary care[.]" Id. (quoting Honeyman v. Hoyt (In Re Carter Wallace, Inc. Sec. Litig.), 220 F.3d 36, 39 (2d Cir. 2000).

In sum, all of Plaintiff's claims fail to allege the scienter element of securities fraud because Plaintiff has

not alleged facts that satisfy either the motive or conscious misbehavior/recklessness prong of scienter.

D. Economic Loss and Loss Causation

Even accepting plaintiff's factual allegations as true and drawing all reasonable inferences in favor of Plaintiff, Karedes, 423 F.3d at 113, Plaintiff has not alleged loss causation with respect to the Paxil Pediatric Allegations, the Paxil Withdrawal Allegations, or the False Claims Act Allegations. One of Plaintiff's class representative certifications, executed under penalty of perjury, states that Plaintiff acquired 1400 GSK shares on September 28, 2001 for $56.28 per share and sold the same number of shares on June 13, 2002 for $39.43 per share. Although Plaintiff suffered an overall loss on the sale of these shares, the SAC fails to allege that a misrepresentation by Defendants, when revealed to the public, was the proximate cause of any loss suffered by Plaintiff. Dura Pharmaceuticals, 544 U.S. at 346-347. A second certification states that Plaintiff purchased 350 shares of GSK on February 17, 2004 at $42.96 and still held those shares as of the date of the certification, May 10, 2005. With respect to these shares, too, Plaintiff fails to allege any particular loss after February 17, 2004

proximately caused by public revelation of Defendants' alleged misrepresentations.

The SAC alleges two GSK share price declines in connection with the Paxil Pediatric Allegations. The first occurred on June 2, 2004, when the New York State Attorney General announced a lawsuit concerning suppression of the Paxil pediatric studies. On that date, GSK shares fell from $42.77 to $41.39. The only other alleged decline occurred on December 9, 2004, when GSK stock price dropped from $45.08 to $44.82 in reaction to a news program highlighting Paxil's effects on children. Plaintiff's certifications show that he held the stock at the time of both alleged price declines, but the SAC fails to allege that Plaintiff suffered a loss. The share price prior to the initial negative market reaction was $42.77, and the share price after the second negative market reaction was $44.82, or $2.05 higher. The SAC, therefore, fails to allege that Plaintiff suffered a loss proximately caused by the truth about Paxil's effects on children reaching the public. In fact, the Paxil Pediatric Allegations fail to allege a loss at all, given that Plaintiff purchased his shares for $42.96 on February 17, 2004 and still held those shares at $44.82, or $1.86 higher, on the date of the second alleged price decline.

The only alleged price decline linked to the Paxil Withdrawal Allegations occurred on September 6, 2001, when news of a class action lawsuit caused GSK shares to fall from $45.14 to $44.10. Here, too, Plaintiff has failed to allege a loss for the simple reason that he did not own GSK stock at the time of the only alleged price drop. Plaintiff made his initial purchase of GSK stock on September 28, 2001, three weeks after the alleged fall in share price. Accepting as true the facts put forward by Plaintiff, the only reasonable inference is that Plaintiff, if anything, benefited from a drop in share price due to disclosures made prior to his purchase of stock, not that he suffered a loss as a result of misrepresentations that came to light.

Plaintiff has also failed to plead loss causation with respect to the False Claims Act allegations. Here, news of a class action lawsuit is alleged to have caused a decline in stock price from $53.96 to $49.40 between November 16, 2001 and December 11, 2001. This decline could not possibly have been caused by the only alleged misleading statement made by GSK with respect to the False Claims Act litigation. The alleged misleading statement regarding settlement of GSK's False Claims Act liabilities was made on April 16, 2003, a full 16 months after the alleged stock

price decline. Plaintiff did not own GSK stock in April 2003 and cannot allege a loss based on a share price decline in that month.

For all of the above reasons, GSK has failed to allege loss causation with respect to the Paxil Pediatric, Paxil Withdrawal, and False Claims Act Allegations.

IV. Control Person Liability

Plaintiff has failed to state a primary violation of the securities laws under section 10(b). Without a primary violation, there can be no secondary, or derivative, violation under Section 20(a). See Shields v. Citytrust Bancorp, Inc., 25 F.3d 1124, 1132 (2d Cir. 1994); Brown v. Hutton Group, 795 F. Supp. 1317, 1324 (S.D.N.Y. 1992). Accordingly, Plaintiff's Section 20(a) claim is also dismissed.

V. Dismissal with Prejudice

Prior to the filing of the motion to dismiss, Plaintiff was given the opportunity to correct deficiencies pointed out by Defendants, with the understanding that no further amendments would be permitted. Plaintiff availed himself of this opportunity prior to serving the

Consolidated Second Amended Complaint. In addition, the grounds for dismissal set forth above demonstrate that further amendment would be futile. Accordingly, the dismissal is with prejudice.

Conclusion

For the reasons stated herein, Defendants motion to dismiss the complaint (dkt. no. 13) is granted, and the Consolidated Second Amended Complaint is dismissed with prejudice.

The Clerk of the Court is directed to mark this action closed and all pending motions denied as moot.

SO ORDERED

October 6, 2006

Loretta A. Preska,
U.S.D.J.